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10/601,171	06/23/2003	Gerald W. Fischer	SYNI-003CN	4940

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EXAMINER	
ARCHIE, NINA	

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1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,171	FISCHER ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-63,65,66,77,79-81,86,87,91,93-101 and 104-115* is/are pending in the application.

4a) Of the above claim(s) *96-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-63,65,66,77,79-81,86,87,91,93-95,101 and 104-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's response filed 7-17-09. Claims 61-63, 65-68, 77, 79-81, 86-87, 91, 93-100, and 104-115 are pending. Claim 61 has been amended. Claims 61-63, 65-66, 77, 79-81, 86-87, 91, 93-95, 101, 104-115 are under examination. Claims 96-100 are withdrawn. Claims 67-68 are cancelled.

Information Disclosure Statement

2. The information disclosure statement filed on 7/17/2009 has been considered. An initialed copy is enclosed.

Rejections Withdrawn

3. In view of the Applicant's amendment and remark following rejections are withdrawn.

a) The objection to claim 67 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of applicants cancellation of claim.

b) The rejection to claims 77, 81, 86-87, 93, and 104-115 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 53-58, 79-83, 91-92, and 96 of copending Application No. 11/193,440 is withdrawn in light of instant application presently granted **US Patent No. 7,511,122** (see rejection below).

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. The rejection of claims 61, 77, 79, 93 and 95 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-12, and 14-19 of U.S. Patent No. 6,610,293 are maintained for the reasons set forth in the previous office action.

Applicants states in Applicants Arguments/Remarks on 7/17/09, will consider filing a terminal disclaimer over the 6,610,293.

5. The rejection of claims 77, 79-81, 86-87, and 93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-43, 47-68 and 72 of copending Application No. 10/323,926 are maintained for the reasons set forth in the previous office action.

Applicants states in Applicants Arguments/Remarks on 7/17/09, will address any obviousness-type double patenting issues upon an indication of allowance claims in Application NO. 11/323,926.

6. The rejection of claims 61, 101 and 104-115 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-12, and 14-19 of U.S. Patent No. 6,610,293 are maintained for the reasons set forth in the previous office action.

Applicants states in Applicants Arguments/Remarks on 7/17/09, will consider filing a terminal disclaimer over the 6,610,293.

Claim Rejections Maintained

35 USC § 112

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The rejection of claims 61-63, 65-66, 79-81, 86-87, 91, 94, 101, and 114-115 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 112, first paragraph, July 14, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicants argue the only element required, for adequate written description of an antibody is the disclosure of a fully characterized antigen and because the only element needed is the disclosure of a fully characterized antigen, the epitope variability is not relevant. Applicants state the monoclonal antibodies specifically bind poly-glycerolphosphate of LTA of Gram positive bacteria. Applicants state poly-glycerol phosphate is a fully characterized antigen and its chemical structure is described in the present specification and was well known in the art at the time of filing (e.g., see Fisher et al. On the basic structure of poly(glycerolphosphate) lipoteichoic acids. Biochem. Cell Biol. vol. 68, 1990, submitted herewith as Appendix A). Applicants argue that because the LTA backbone is composed of repeating units of poly-glycerol phosphate, it represents a small number of defined and well characterized epitopes. Applicants argue because the present claims are directed to antibodies that bind a fully characterized antigen, namely poly- glycerol phosphate of LTA of Gram positive bacteria, the written description requirement has been met. Applicants argue that as stated by the Board in Ex Parte Xia, the specific epitope recognized by the antibody need not be disclosed. Applicants argue there is a correlation between the structure of a monoclonal antibody which specifically binds poly-glycerol phosphate of LTA and the function of binding to and enhancing opsonization of Staphylococcus epidermidis, coagulase negative staphylococci, Staphylococcus aureus and

Streptococcus mutans provided in the specification (see e.g., Examples 2, 3 and 7). Applicants state at least 3 antibodies of the claimed genus (see e.g., Examples 1-13) have been described.

Examiner's Response to Applicants Arguments:

In response to Applicants statement as set forth supra, Applicants responses in regards to the only element needed for adequate written description of an antibody is the disclosure of a fully characterized antigen and the epitope variability is not relevant is unpersuasive. To begin with, the instant claims are drawn to a composition comprising a monoclonal antibody with the recited characteristics of a) prevent any and all staphylococcal infections in neonates, b) bind to poly-glycerol phosphate of LTA, and c) enhance opsonization of *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus*, and *Streptococcus mutans*. However, the specification only provides limitations for the following disclosures from the specification summarized below. The specification discloses MAB 96-110 against Lipotechoic Acid from bacteria such as *Streptococcus mutans, Staphylococcus aureus, Streptococcus faecalis, and Streptococcus pyogenes* (Example 7 Table 8 pg. 52-55). Additionally, the specification discloses the chimeric monoclonal antibody/monoclonal antibody 96-110 bound to both coagulase positive and negative and enhanced opsonization (see pgs. 45-46 Examples 2). Moreover the specification discloses anti-LTA MAB for *Staphylococci* epidermidis that demonstrates enhanced opsonic activity (see pgs. 66-67 Example 11). Also the specification discloses in vivo efficacy administering chimeric monoclonal antibody (chimeric MAB) /monoclonal 96-110 (MAB 96-110) which shows survival of mice but not prevention of any staphylococcal infection (Examples 3 and 12-13 pgs. 67-71). Applicants have only shown examples that demonstrate an increase in neonatal survival against specific bacteria not protection nor passive immunization against all staphylococcal species using specifically MAB 96-110. The specification discloses 96-110 monoclonal antibody to be strongly reactive to methanol fixed S. epidermidis and bound to S. epidermidis (Strain Hay). The specification discloses 96-110 monoclonal antibody reacted with S. aureus type 5 (SA5) and S. aureus type 8 (SA8) (see pgs. 35-41). The specification discloses 96-110 monoclonal antibody binding to the surface protein on S. epidermidis (Strain Hay) that bound broadly to opsonic antibody and also the specification discloses said IgG1 MAB raised against S. epidermidis (Strain Hay) that binds to the surface of both coagulase negative and coagulase (see pgs. 35-41). Furthermore, although the specification discloses several

hybridoma clones that were tested for the recited characteristics, Applicants have only demonstrated 96-110 monoclonal antibody (mouse IgG1 MAB) of IgG1 isotype produce from hybridoma in example 1 capable of the recited characteristics aforementioned above. Moreover, the LTA is derived from a "unique" strain (i.e. the Hays strain) indicating a variation of the LTAs among staphylococcal species. Consequently, out of all the hybridoma clones they produced in example 1, only 1 (96-110 monoclonal antibody (mouse IgG1 MAB)) had the claimed characteristics. Moreover, because said monoclonal antibody is capable of binding to LTA from S. epidermidis (Strain Hay), Applicants have not shown that 96-110 monoclonal antibody or the genus of monoclonal are capable of binding to all LTA since LTA is not identical in all gram positive bacteria. Therefore Applicant have only contemplated that a composition comprising any monoclonal antibody possesses all the recited characteristics of the claimed monoclonal antibodies. Consequently, the number of species disclosed by the specification is not representative of a monoclonal antibody of IgG isotype and is not deemed to be representative of the genus encompassed by the instant claims. Applicant is reminded that adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Therefore the written description rejection is maintained.

As outlined previously, the instant claims are drawn to a composition comprising an amount of a monoclonal antibody effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier, wherein the antibody specifically binds to poly- glycerol phosphate of Lipoteichoic acid (LTA) of Gram positive bacteria and is of the IgG isotype, wherein the antibody binds to and enhances opsonization of multiple serotypes of *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus*, and *Streptococcus mutans* by phagocytic cells with or without complement as compared to an appropriate control in an in vitro opsonization assay.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of

the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of a composition comprising a monoclonal antibody with the recited characteristics, applicant must adequately describe the antigenic determinants (immunocpitopes) based on the ability to a) prevent any and all staphylococcal infections in neonates, b) bind to poly-glycerol phosphate of LTA, and c) enhance opsonization of *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus*, and *Streptococcus mutans*.

The specification discloses the chimeric monoclonal antibody/monoclonal antibody 96-110 bound to both coagulase positive and negative and enhanced opsonization (see pgs. 45-46 Examples 2). The specification discloses anti-LTA MAB for *Staphylococci* epidermidis and demonstrates enhanced opsonic activity (see pgs. 66-67 Example 11). The specification discloses in vivo efficacy administering chimeric monoclonal antibody (chimeric MAB) /monoclonal 96-110 (MAB 96-110) which shows survival of mice but not prevention of any staphylococcal infection (Examples 3 and 12-13 pgs. 67-71). The specification discloses MAB 96-110 against Lipotechoic Acid from bacteria such as *Streptococcus mutans, Staphylococcus aureus, Streptococcus faecalis, and Streptococcus pyogenes* (Example 7 Table 8 pg. 52-55). These disclosures do not provide adequate description of the claimed genus of antibodies.

Applicants have only shown examples that demonstrate an increase in neonatal survival against specific bacteria not protection against all staphylococcal species using specifically MAB 96-110. The specification discloses 96-110 monoclonal antibody to be strongly reactive to methanol fixed S. epidermidis and bound to S. epidermidis (Strain Hay). The specification discloses 96-110 monoclonal antibody reacted with S. aureus type 5 (SA5) and S. aureus type 8 (SA8) (see pgs. 35-41). The specification discloses 96-110 monoclonal antibody binding to the surface protein on S. epidermidis (Strain Hay) that bound broadly to opsonic antibody and also the specification discloses said IgG1 MAB raised against S. epidermidis (Strain Hay) that binds to the surface of both coagulase negative and coagulase (see pgs. 35-41). Furthermore, although the specification discloses several hybridoma clones that were tested for the recited characteristics, Applicants have only demonstrated 96-110 monoclonal antibody (mouse IgG1 MAB) of IgG1 isotype produce from hybridoma in example 1 capable of the recited

characteristics aforementioned above. Moreover, the LTA is derived from a "unique" strain (i.e. the Hays strain) indicating a variation of the LTAs among staphylococcal species. Consequently, out of all the hybridoma clones they produced in example 1, only 1 (96-110 monoclonal antibody (mouse IgG1 MAB)) had the claimed characteristics. Moreover, because said monoclonal antibody is capable of binding to LTA from S. epidermidis (Strain Hay), Applicants have not shown that 96-110 monoclonal antibody or the genus of monoclonal are capable of binding to all LTA since LTA is not identical in all gram positive bacteria. Therefore Applicant have only contemplated that a composition comprising any monoclonal antibody possesses all the recited characteristics of the claimed monoclonal antibodies. Consequently, the number of species disclosed by the specification is not representative of a monoclonal antibody of IgG isotype and is not deemed to be representative of the genus encompassed by the instant claims.

The limited number of composition comprising a monoclonal antibody of IgG isotype disclosed is not deemed to be representative of the genus encompassed by the instant claims. The specification, does not disclose distinguishing and identifying features of a representative number of members of the genus of a composition comprising a monoclonal antibody of the IgG isotype, to which the claims are drawn, such as a correlation between the structure of the immunoepitope and its recited function (a) prevent staphylococcal infections in neonates, b) wherein said antibody binds to poly-glycerol phosphate of LTA, and c) and which enhances opsonization of the *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus*, and *Streptococcus mutans*), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of a composition comprising a monoclonal antibody of the IgG isotype.

Moreover the specification fails to disclose the protective immunoepitope(s) of a composition comprising a monoclonal antibody. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of the monoclonal antibody aforementioned above to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of a composition comprising a monoclonal antibody of the IgG isotype possessing the recited functions.

Moreover a vaccine is defined as "a prophylactic or therapeutic material containing antigens derived from one or more pathogenic organisms which, on administration to man or animal, will stimulate active immunity and protect against infection with these or related organism (i.e. produce protective immunity)." (The Dictionary of Immunology, Herbert et al eds, Academic Press, 1995).

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant

shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of a composition comprising a monoclonal antibody with the recited activities. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of a composition comprising a monoclonal antibody to which the claims refer and therefore the claimed invention is not properly disclosed.

Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

8. The rejections of claims 77, 79-81, 86-87, 91, 93-95, and 104-113 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

Applicants arguments filed in response to the 35 U.S.C. 112, first paragraph, July 14, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicants Arguments:

Applicants argue because the claimed antibodies, or antigen binding fragments thereof are directed to a fully characterized antigen, and, alternatively, because the claimed antibodies are described to have a clear correlation between their structure and function meets the written description requirement.

Examiner's Response to Applicants Arguments:

In response to Applicants statement as set forth supra, the instant claims are drawn to a composition comprising a monoclonal antibody with the recited characteristic of binding to poly-glycerol phosphate of LTA of a Gram positive organism and not just those determinants that would bind to poly-glycerol phosphate of LTA itself, is unpersuasive because the "antigens" encompassed by the claims has not been described since LTA is not identical in all gram positive bacteria only the LTA from S. epidermidis (Hay Strain). The specification only provides limitations for the following disclosures from the specification summarized below. Consequently, out of all the hybridoma clones they produced in example 1, only 1 (96-110 monoclonal antibody (mouse IgG1 MAB)) had the claimed characteristics. The specification discloses the chimeric monoclonal antibody monoclonal antibody 96-110 bound to both coagulase positive and negative and enhanced opsonization (see pgs. 45-46 Examples 2). The specification discloses anti-LTA MAB for Staphylococci epidermidis and demonstrates enhanced opsonic activity (see pgs. 66-67 Example 11). The specification discloses MAB 96-110 against Lipotechoic Acid from bacteria such as Streptococcus mutans, Staphylococcus aureus, Streptococcus faecalis, and Streptococcus pyogenes (Example 7 Table 8 pg. 52-55). Moreover,

the LTA is derived from a "unique" strain (i.e. the Hays strain) indicating a variation of the LTAs among staphylococcal species. Although that said 96-110 monoclonal antibody is capable of binding to LTA from S. epidermidis (Strain Hay), Applicants have not shown that 96-110 monoclonal antibody or the genus of monoclonal are capable of binding to all LTA since LTA is not identical in all gram positive bacteria. Moreover, Applicant has not demonstrated that a composition comprising variants of a monoclonal antibody of IgG isotype aforementioned above is capable of specifically binding to poly-glycerol phosphate of LTA of all gram positive bacteria species and not just those determinants that would bind to poly-glycerol phosphate of a given LTA itself of the claimed invention. Furthermore, one skilled in the art cannot envision all the contemplated variants and antigen binding fragments of the monoclonal antibody aforementioned above. Therefore the specification provides insufficient written description to support the genus encompassed by the claim.

As outlined previously, the independent claim 77 and all dependent claims 77, 79-81, 86-87, 91, and 93-95, is drawn to a composition comprising a monoclonal antibody, which specifically binds to a polyglycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises the complementarity determining regions (CDRs) of the heavy and light chain variable regions of monoclonal antibody 96-110 as set forth as SEQ ID NO: 87 and SEQ ID NO: 89.

Moreover, as outlined previously, the independent claims 104-105 are drawn to a composition comprising a monoclonal antibody, which specifically binds to a polyglycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody of the heavy chain (claim 104) and light chain (claim 105) variable regions of monoclonal antibody as set forth as SEQ ID NO: 87 (claim 104) and SEQ ID NO: 89 (claim 105).

Moreover, as outlined previously, the independent claims 106 and 110 and all dependent claims 107-109 and 111-113 are drawn to a composition comprising a monoclonal antibody, wherein the monoclonal antibody comprises a heavy chain comprising the heavy chain complementarity determining regions (CDRs) of the monoclonal antibody 96-110 and variable region having 80% (claim 106) , 85% (claim 107), 90% (claim 108), and 95% (claim 109) amino

acid identity with SEQ ID NO: 87; and light chain comprising the light chain complementarity determining regions (CDRs) of the monoclonal antibody 96-110 and variable region having 80% (claim 110), 85% (claim 111), 90% (claim 112), and 95% (claim 113) amino acid identity with amino acid identity with SEQ ID NO: 89.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

To adequately describe the genus of compositions comprising a monoclonal antibody with the recited characteristics, applicant must adequately describe the antigenic determinants (immunoepitopes) that convey the ability to bind to poly-glycerol phosphate of LTA of a Gram positive organism not just those determinants that would bind to poly-glycerol phosphate of LTA itself.

The specification discloses the chimeric monoclonal antibody/monoclonal antibody 96-110 bound to both coagulase positive and negative and enhanced opsonization (see pgs. 45-46 Examples 2). The specification discloses anti-LTA MAB for *Staphylococci* epidermidis and demonstrates enhanced opsonic activity (see pgs. 66-67 Example 11). The specification discloses MAB 96-110 against Lipotechoic Acid from bacteria such as *Streptococcus mutans, Staphylococcus aureus, Streptococcus faecalis, and Streptococcus pyogenes* (Example 7 Table 8 pg. 52-55). Consequently, out of all the hybridoma clones they produced in example 1, only 1 (96-110 monoclonal antibody (mouse IgG1 MAB)) had the claimed characteristics.

The data indicated above does not correlate to the claimed functions set forth in the instant claims. Moreover, the LTA is derived from a "unique" strain (i.e. the Hays strain) indicating a variation of the LTAs among staphylococcal species. Although that said 96-110 monoclonal antibody is capable of binding to LTA from S. epidermidis (Strain Hay), Applicants have not shown that 96-110 monoclonal antibody or the genus of monoclonal are capable of binding to all LTA since LTA is not identical in all gram positive bacteria. Moreover, Applicant

has not demonstrated that a composition comprising variants of a monoclonal antibody of IgG isotype aforementioned above is capable of specifically binding to poly-glycerol phosphate of LTA of all gram positive bacteria species and not just those determinants that would bind to poly-glycerol phosphate of a given LTA itself of the claimed invention.

The specification, however, does not disclose distinguishing and identifying features of a representative number of members of the genus aforementioned above to which the claims are drawn, such as a correlation between the structure of the immunoepitope and its recited function (binding to poly-glycerol phosphate of LTA), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of compositions aforementioned above. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Also the specification fails to disclose which variable regions of the heavy and light chain of a monoclonal antibody of SEQ ID NO: 87 and 89; and of the monoclonal antibody 96-110 that are essential to the function of the immunoepitope and are able to retains its the activity. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of the compositions comprising a monoclonal antibody aforementioned above to which the claims are based capable binding specifically to poly-glycerol phosphate of LTA.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere

statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might

profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Furthermore the specification lacks written description of the instant variants that specifically bind to polyglycerol phosphate of LTA. For example, Colman et al. (Research in Immunology 145: 33-36, 1994, p.33 column 2, p. 35 column 1) disclose that a single amino acid changes in an antigen can effectively abolish the interaction with an antibody entirely and that a very conservative amino acid substitution may abolish antibody binding and a non-conservative amino substitution may have little effect in antibody binding. This underlies the importance of the description of the immunoepitopes that are protective and which conservative amino acid substitutions and where and how many changes can the immunoepitopes tolerate and still retain the ability to protect from infection. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of compositions comprising a monoclonal antibody with the claimed characteristics, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of compositions aforementioned above capable of binding specifically to poly-glycerol phosphate of LTA on Gram positive bacteria. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of compositions comprising a monoclonal antibody aforementioned above, to which the claims refer and therefore the claimed invention is not properly disclosed.

Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Enablement

9. The rejection of claims 61-63, 65-66, 79-81, 86-87, 91, 94, and 101, and 114-115 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for the reasons set forth in the previous office action. The claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants Arguments:

A) Applicants state, the Examiner insists that the specification is limited to survival of neonates and cannot be drawn to prevention of staphylococcus infection based upon the Examiner's construction of the term "prevention" to be equivalent to administration of a vaccine. Applicants argue the present claims are not directed to a vaccine or an active immunization in which an antigen or fragment thereof is administered to a host to induce a protective immune response to antigen; instead, the present invention is directed to a composition comprising anti-LTA monoclonal antibodies which have been shown to opsonize multiple Gram positive bacteria and to protect against infection when administered in vivo. Applicants state the specification describes protective administration of a composition and a method of preventing such infections, comprising administering a prophylactically effective amount of a pharmaceutical composition comprising the anti-LTA antibody (whether polyclonal or monoclonal or chimeric, including fragments, regions, and derivatives thereof) and a pharmaceutically acceptable carrier (see page 23). Applicants state the specification provides ample guidance for producing the presently claimed antibodies, specifically provides 13 Examples describing antigen preparation, antibody and hybridoma creation (Example 1), tests for opsonic activity (Examples 2 and 11), description and testing of in vivo protection (Examples 3 and 12), binding and antigen characterization (Examples 4-7), humanization (Example 8), and chimeric antibody production (Examples 9 and 10). Applicants submit that the evidence of increased survival shown in Examples 3 and 12 is affirmative evidence of protection and therefore prevention of Staphylococcal infection.

B) Applicants state the Examiner's discussion and the cited references are not relevant because the present invention is not drawn to methods of active immunization, but, as described above, to administration of a composition of anti-LTA antibodies to neonates to prevent Staphylococcal infection. Applicants cite several references that disclose how antibody compositions have been successfully used to treat or prevent infection by a wide variety of pathogenic agents including viruses, bacteria, and toxins. Applicant state Volk et al. disclose antibody compositions directed to tetanus toxin are used in the clinic to protect patients who are potentially exposed to tetanus. Applicants state Meuleman et al. showed that prophylactic administration of anti-CDS1 antibodies was effective at preventing Hepatitis C virus infection in animals. Applicants state Rosok et al. found that administration of monoclonal antibodies against

the flagellum of Pseudomonas aeruginosa " which received antibody injections prior to bacterial infection survived, as compared to about 20% survival in control animals and also showed that the monoclonal antibodies were effective for treating animals after infection, where 70%-90% of treated post- infection animals were protected. Applicants state Example 3 of showed that administration of an antibody composition of the invention prior to and after bacterial infection enhanced survival in a rat neonate model and Example 12 of the further shows protective efficacy of a chimeric antibody of the invention for Adult CF1 mice against bacterial infection, while Example 13 shows efficacy of the chimeric antibody in a neonatal rat model. Applicants argue the specification demonstrates the efficacy of administering a composition of anti-LTA antibodies to treat or prevent Staphylococcal infection. Applicants state FDA approved the drug Synagis® (Palivizumab) as a protective antibody, whereby the manufacturer states the drug is not a vaccine but provides virus-fighting substances called antibodies that help prevent RSV. In addition, Applicants argue the administration of said drug prior to RSV infection to prevent disease is a regular administration although said administration of drug may be continued after infection.

Examiner's Response to Applicants Arguments:

In response to applicants statement in (A) as set forth supra, in regards to Applicants response that the present invention is directed to a composition comprising anti-LTA monoclonal antibodies which have been shown to opsonize multiple Gram positive bacteria and to protect against infection when administered in vivo; the claims are also drawn to a specific monoclonal antibody of IgG isotype effective to prevent staphylococcal infection in neonates which have been shown to opsonize multiple serotypes of specific Gram positive bacteria as claimed. Although Applicants state the claimed invention is not used in terms of prevention but passive immunization, the instant invention only contemplates passive immunization for all staphylococcal species since only the 96-110 monoclonal antibody of IgG isotype possessed all characteristics of the claimed invention and specifically the characteristic of the LTA bound to said monoclonal antibody is derived from a "unique" strain (i.e. the Hays strain) of S. epidermidis indicating that a variation of the LTAs among staphylococcal species. Moreover, the claims are specifically limited to prevention not passive immunization. However, the claimed

invention encompasses prevention of staphylococcal infection in neonates which further encompasses infections of the skin such as impetigo (a crusting of the skin) or cellulitis (inflammation of the connective tissue under the skin, leading to swelling and redness of the area) and staphylococcal sepsis (infection in the bloodstream); the prevention is correlated to a vaccine. Therefore as stated in the previous office action a vaccine by definition must provide protection against an infection demonstrable by challenge experiments. Moreover, Applicants disclosure of several examples aforementioned and stating that increased survival shown in Examples 3 and 12 demonstrate an increase in neonatal survival against specific bacteria not protection (nor passive immunization as indicated by Applicant above) against all staphylococcal species using specifically MAB 96-110. The specification only contemplates that the survival of neonates leads to prevention. Hence, the specification is only limited to the survival of neonates through the administration of the MAB 96-110 as indicated in the previous office action. Furthermore, the clearance of the staphylococci from the blood with a chimeric monoclonal antibody/monoclonal antibody 96-110 (see pg. 71) also does not indicate prevention. Consequently, Applicants have only shown examples that demonstrate an increase in neonatal survival against specific bacteria not protection against all staphylococcal species using specifically MAB 96-110. Therefore the rejection is maintained.

In response to Applicants statement in (B) as set forth supra, the references cited by Applicant are not relevant to the claims because the present invention is specifically directed to the composition: comprising a monoclonal antibody of IgG isotype effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier. Furthermore, in regards to Applicants stating the claimed invention is not used in terms of prevention but passive immunization is unpersuasive, because the only 96-110 monoclonal antibody of IgG isotype possessed all characteristics of the claimed invention and specifically the characteristic of LTA bound to said monoclonal antibody is derived from a "unique" strain (i.e. the Hays strain) of S. epidermidis indicating that a variation of the LTAs among staphylococcal species. Moreover, the claims specifically limited to prevention not passive immunization. Applicants have not demonstrated passive immunization for all staphylococcal species Moreover, even though Example 3 shows the administration of an antibody composition of the claimed invention prior to

and after bacterial infection which enhanced survival in a rat neonate model and also Example 12 showing only therapeutic efficacy of a chimeric antibody of the claimed invention is not indicative of any empirical data or results displaying prevention or passive immunization against Staphylococcus infection as claimed in neonates which further encompasses infections of the skin such as impetigo (a crusting of the skin) or cellulitis (inflammation of the connective tissue under the skin, leading to swelling and redness of the area) and staphylococcal sepsis (infection in the bloodstream). Therefore, one skilled in the art would not accept on its face the examples given in the specification as being correlative or representative of a successful model. In regards to Applicants responses that the FDA approved antibody compositions showing the example of the drug Synagis® (Palivizumab) as a protective antibody; on the contrary, Applicants indicated the manufacturer states virus-fighting substances called antibodies helps in prevention of RSV infection, however although FDA approved a protective antibody because said antibody helps in prevention is not the issue in the instant enablement rejection for the claimed invention.

Therefore Applicants responses aforementioned above are unpersuasive and the rejection is maintained.

As outlined previously, the specification is not enabled for a composition comprising an amount of an isolated a monoclonal antibody effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier. Furthermore, the specification does not reasonably enable any composition comprising an amount of an isolated a monoclonal antibody effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

(A) The nature of the invention;

(B) The breadth of the claims;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The instant claims are drawn to any composition: comprising an amount of an isolated a monoclonal antibody of IgG isotype effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier.

Breadth of the claims: The claims encompass any composition: comprising an amount of an isolated a monoclonal antibody which specifically binds to poly- glycerol phosphate of Lipoteichoic acid (LTA) of Gram positive bacteria and is of the IgG isotype, binds to and enhances opsonization of multiple serotypes of *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus*, and *Streptococcus mutans* by phagocytic cells with or without complement as compared to an appropriate control in an in vitro opsonization assay and is effective to prevent any type of staphylococcal infection in neonates (which encompasses infections of the skin such as impetigo (a crusting of the skin) or cellulitis (inflammation of the connective tissue under the skin, leading to swelling and redness of the area) and staphylococcal sepsis (infection in the bloodstream).

Guidance of the specification/The existence of working examples:

The specification discloses in vivo efficacy administering chimeric monoclonal antibody (chimeric MAB) /monoclonal 96-110 (MAB 96-110) which shows survival of mice but not prevention (Examples 3 and 12-13 pgs. 67-71). There was no prevention against any type of *Staphylococcus* species offered by chimeric monoclonal antibody/monoclonal antibody 96-110, indicating that immunization with chimeric monoclonal antibody/monoclonal antibody 96-110 alone is insufficient to elicit protection in contrast to the claimed invention. The specification discloses chimeric monoclonal antibody/monoclonal antibody 96-110 promote clearance of the

staphylococci from the blood (see pg. 71). However, the specification is only limited to the survival of neonates through the administration of the MAB 96-110. Consequently, Applicants have only shown examples that demonstrate an increase in neonatal survival against specific bacteria not protection against all staphylococcal species using specifically MAB 96-110. The claimed invention is drawn to prevention of staphylococcal infection and as result prevention is correlated to a vaccine. A vaccine by definition must provide protection against an infection demonstrable by challenge experiments. The data as set forth supra does not demonstrate that the composition confers "protection" against infection by *Staphylococcus*. The data merely shows that said composition increases the number of neonates that survived from *Staphylococcus* infection. Therefore the data fails to show prevention or vaccine protection against *Staphylococcus* species. Therefore, one skilled in the art would not accept on its face the examples given in the specification as being correlative or representative of a successful model. The working examples do not disclose any empirical data or results indicative of a preventing *Staphylococcus* infection as claimed. The specification is devoid of any teaching that the claimed prevents staphylococcal infection in neonates.

State of the art: Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrasekhar et al., US Patent 6,248,329, col. 1, lines 35-41). It is well recognized in the vaccine art, that it is unclear whether an antigen derived from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plotkin, et al. (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.., and thus protect the host against attack by the pathogen." As evidenced by Greenspan et al. (*Nature Biotechnology* **7**: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are

energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. For the reasons set forth supra, the state of the art is has limitations to a composition comprising a monoclonal antibody aforementioned above and the state of the art is unpredictable with regard any composition as set forth supra comprising a monoclonal antibody.

In conclusion, the claimed invention is not enabled for any composition comprising an amount of an isolated a monoclonal antibody effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention. The claims encompass any composition: comprising an amount of an isolated a monoclonal antibody of IgG isotype effective to prevent any type of staphylococcal infection in neonates which encompasses infections of the skin such as impetigo (a crusting of the skin) or cellulitis (inflammation of the connective tissue under the skin, leading to swelling and redness of the area) and staphylococcal sepsis (infection in the bloodstream). The specification fails to teach that the composition as set forth can produce a protective response in the host, for prevention of staphylococcal in neonates, as is requisite of a vaccine composition. The state of the art teaches that there are limitations to a vaccine composition and the state of the art is unpredictable. In view of the lack of support in the art and specification for an effective vaccine, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed composition.

New Grounds of Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 77, 79-81, 86-87, 93, 101, and 104-115 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122.

Claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122 teach a composition comprising an amount of an isolated monoclonal antibody (humanized/chimeric antibody) which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises the heavy/light chain variable region set forth as SEQ ID NO.87 and SEQ ID NO. 89. Furthermore , U.S. Patent No. 7,511,122 teach a composition comprising an amount of an isolated monoclonal antibody (humanized/chimeric antibody) which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises a heavy/light chain comprising the heavy/light chain complementarity determining regions (CDRs) of the monoclonal antibody 96-110 and a variable region having 80% amino acid identity with SEQ ID NO:87 and SEQ ID NO:89 and having at least 70% amino acid identity with the monoclonal antibody 96-110 heavy/light chain variable region set forth as SEQ ID NO: 87 and SEQ ID NO: 89.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Patent No. 7,511,122 recites the "humanized/chimeric antibody". The species of the humanized/chimeric antibody anticipate the genus claims of any monoclonal antibody. Thus, claims 77, 79-81, 86-87, 93, 101, and 104-115 encompassing the monoclonal antibody in the present application are obvious over claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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/Robert B Mondesi/
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